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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,504	10/26/2001	Yi-Ren Woo	1416.03US01	4675

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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,504	WOO ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 40-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 40-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 09/28/2005 have been fully considered but they are not persuasive. With regard to the arguments of pages 7-8, stents are inherently rigid since they need to hold open a vessel and once deployed are non-deformable. In the broadest reasonable interpretation of the term "rigid", the stents of Alt, Dayton and Solovay can be considered rigid and as defined by applicant are non-deforming ("do not deform with a visible shape change upon contact with a vascular system experiencing physiologic blood pressure" [0043]). With regard to the arguments against the Alt and Solovay references regarding separate layers, both reference have pores are "formed in the rigid material" (the material is a composite of layers one of which is porous) and the pores substantially extend through the rigid material (in the case of Alt transverse the thickness and in the case of Solovay through the thickness). The characterization that the present invention does not include a second porous layer carries no weight since the claims do not so limit the structure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 40-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. There is no support for the "non-deformable component" added to claims 1, 40 and 49. The closest discloser is "rigid materials are materials that do not deform with a visible shape change upon contact with a vascular system experiencing physiologic blood pressure" ([0043]) which does not reasonable convey a "non-deformable component".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 15-19, 40-45, 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (US 6099561). Alt discloses an implantable prosthesis (fig. 1A, embodiment '053) comprising non-deformable component (once deployed the stent of Alt is non-deformable in as much as is defined by the current application, i.e. do not deform with a visible shape change upon contact with a vascular system experiencing physiologic blood pressure [0043]) a rigid material (metal) with pores (col 5 line 19), wherein a filler comprising a bioactive agent (drugs, col 5, line 23) thereof, is located within the pores, wherein said rigid porous material with the filler presents a smoother surface for fluid flow than pores without filler (this is inherent since a filled pore presents less surface roughness).

With regard to claims 3, 43 and 52, as presented in claim 1 the filler presents a smooth surfaces to flow as compared to unfilled.

With regard to claim 4, filled pores are partly filled pores.

With regard to claims 5-8, 10, 18-19, 44 and 53, these claims are non-elected since Alt meets the Markush grouping of claim 1 by including a bioactive agent.

With regard to claims 11, 15, 45, 48 and 54, anti-thrombotic (col 5, line 33) is an anticoagulant.

With regard to claims 16-17, Alt's surface consists of bonded spheres which would present pores having interconnecting porosity and since the pores are interconnected, the pores therefore extend through the rigid material (i.e. not through the thickness of the rigid material).

With regard to claim 50, See column 3 lines 54-61

Claims 1-11, 14-15, 18-21 and 40-45 and 47-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Dayton (US 5578075). Dayton discloses an implantable prosthesis (title) comprising non-deformable component (once deployed the stent of Dayton is non-deformable in as much as is defined by the current application, i.e. do not deform with a visible shape change upon contact with a vascular system experiencing physiologic blood pressure [0043]) a rigid material (11, rigid since the stent must hold open the vessel) with pores (claim 1), wherein a filler comprising a bioactive agent (claim 1) thereof, is located within the pores, wherein said rigid porous material with the filler presents a smoother surface for fluid flow than pores without filler (this is inherent since a filled pore presents less surface roughness).

With regard to claims 3, 43 and 52, as presented in claim 1 the filler presents a smooth surfaces to flow as compared to unfilled.

With regard to claim 4, filled pores are partly filled pores.

With regard to claims 5-8, 10, 18-19, 44 and 53, these claims are non-elected since Dayton meets the Markush grouping of claim 1 by including a bioactive agent.

With regard to claims 11, 15, 45, 48 and 54, heparin (col 7, line 24) is an anticoagulant.

With regard to claims 14 and 47, Dayton discloses the use of antibodies (col 7, lines 24-30) which are disclosed in the present application as a progenitor attraction compound.

With regard to claims 20-21, Dayton specifies that the stent maybe made of polyurethane (col 6 last line).

With regard to claim 50, See column 8 lines 1-8

Claims 40-45 and 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Solovay (US 5,769,884). Solovay discloses an implantable medical device comprising non-deformable component (once deployed the stent of Solovay is non-deformable in as much as is defined by the current application, i.e. do not deform with a visible shape change upon contact with a vascular system experiencing physiologic blood pressure [0043]) a rigid material (30) having pores (abstract) and a filler (col 6) comprising hydrogel, a structural protein, a bioactive agent, or a mixture thereof (lines 47-55) to promote cellular attachment and proliferation.

With regards to claims 43 and 52, the filled pores inherently present a smooth surface to flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-13, 46 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Steinke et al (US 6033436). Dayton discloses an implantable prosthesis as discussed above. However, Dayton does not specifically discloses the use VEGF. Steinke et al discloses another implantable prosthesis using VEGF (col 9 lines 57-58) as a bioactive agent to promote angiogenic response. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use VEGF as taught by Steinke et al in the implantable prosthesis as disclosed by Dayton in order to promote angiogenic response.

Allowable Subject Matter

Claims 22 and 23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

This is a RCE of applicant's earlier Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs

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